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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/733,554

12/10/2003

Fred J. Molz IV

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IP Section

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EXAMINER

SWIGER III, JAMES L

ART UNIT

PAPER NUMBER

3775

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/733,554	Applicant(s) MOLZ ET AL.	
	Examiner JAMES L. SWIGER III	Art Unit 3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 42-48,52-57,60 and 61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 42-48,52-57,60 and 61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12/10/2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the **elastic material disposed through both first and second openings** must be shown or the feature(s) canceled from the claim(s).

This limitation is found in claim 42, 60 and 61.

No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 42-48, 52-57 and 60-61 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regards to claim 42 and 60-61 applicant claims a **"flexible member."** It is **noted that applicant also uses the term "joint component."** However, in the first half of the claim, positively recited structure includes a first biocompatible attachment device, a second biocompatible attachment device, and a flexible member (or joint component) attached to these devices. This system is adapted to be flexible with respect to the superior and inferior vertebrae. In the second half of the claim, the applicant further discusses the "flexible member" ("joint component") to include a first and second components as well as an elastic material, which is flexible. It is unclear if applicant is claiming the individual parts which must be flexible relative to the vertebrae, or if applicant is trying to claim that the entire device, shown in Fig. 4, is itself a 'flexible member' ('joint component').

For examination purposes, the claims will be interpreted as shown in the drawings. Since applicant has admitted that the claims may be interpreted in both ways as noted above, this is still unclear because if the second interpretation were the case, the drawings appear to require that the flexible member would also need to have to at

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least 4 (four) elongated portions or legs. This is not shown in the drawings, if this were required by the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 42-48, 52-57 and 60-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lombardo (US Patent 6,238,396) in view of Ferree 2003/0220643).

Lombardo teaches a surgical implant capable of replacing the function of a facet joint comprising a first elongated body attachment device (10) and a second elongated attachment device (20). Each device has the capability of attaching to a pedicle of a vertebrae (see hooks 7). Both of the first and second elongated components have first joint elements with openings. Lombardo also has a member (5) that extends through the joint ends or first and second openings and allows variation in angles of the device. I Elongate item 20 has joint end 25 with an opening. Elongate item 10 has an opening (9/70) in a joint end (11b). Both members may be considered "rigid." Also, in regards to applicant's invention the entire device itself may be considered flexible (see Fig. 4a) as the entire device may be angled as needed for the invention

With regards to various materials such as the elongate components being biocompatible or the member extending through the joint component having elastic properties, it would have been obvious to one having ordinary skill in the art at the time

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the invention was made to include these various property features, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Lombardo discloses the claimed invention except for a covering/connector/or flexible sleeve that surroundings the joint area to assist in the flexible features of the joint. Ferree discloses a spinal fixation device that uses a sleeve as a cushion or protective cover. Ferree discloses many variations and shapes in the sleeves. In par. 26 Ferree further discloses that the sleeves could be made of any compressible or resilient material with cushion-like properties. Though it further discloses in par. 0020 that the sleeve may be placed over springs in preventing spinal extension, it still has a degree of elasticity to assist in the joint area. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Lombardo having at least an elastic/flexible connector in view of Ferree to better protect, connect, and supplement the function of the joint connection of the device to better assist in facet joint replacement.

Response to Arguments

Applicant's arguments filed 10/16/2008 have been fully considered but they are not persuasive. With regards to applicant arguments with regards to the drawing objection, this is not found persuasive. The claims require that the elastic component go through the joint in the first and second openings. The drawings do not show that. The drawings show an olive shaped or partial sphere shape as applicant has noted.

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Applicant pointed out where these shapes are noted in the specification. However, unless pitted, it is known that olives are hollow. Further a partial sphere may or may not be hollow. In any case, the drawings show the joint connection in hidden lines to be represented underneath the surface of the elastic component. Even though applicant also pointed out in paragraph 46 that the elastic material "may flow through both openings" applicant has positively claimed that this elastic material **MUST** flow through both openings. As it is positively claimed subject matter, there is no reason to assume that a hollowed olive, as applicant has clearly drawn in Figs. 4 and 5 actually flows through the joint as disclosed in paragraph 46 and thus the claimed subject matter is not shown in the drawings.

With regards to the rejections under 112, applicant has admitted that the claims may be interpreted in both ways as noted above. This is still unclear because if the second interpretation were the case, the drawings would appear to require that the flexible member would also need to have to at least 4 (four) elongated portions or legs. This is not shown in the drawings, if this were required by the claim.

Further applicant's arguments with regards to the rejection under 35 USC 103 is not found persuasive. Lombardo shows a device that may be secured to the vertebrae and replace the functions of the facet joint. These two elongated portions are connected at a joint. Ferree shows an elastic material that surrounds this joint and provides flexibility to the two elongated portions--causing both dynamic motion as well as a biasing force in securing the vertebrae.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAMES L. SWIGER III whose telephone number is (571)272-5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JAMES L SWIGER/
Examiner, Art Unit 3775

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733